UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,157	09/15/2003	Keith Charles Deen	GH-50017-2	4000

26130 7590 09/27/2004

RATNER & PRESTIA- SB DIVISION
ONE WESTLAKES
SUITE 301
BERWYN, PA 19482

EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,157	DEEN ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement, submitted 13 September 2003, has been entered. Applicant's election of Invention I (claims 1-11 and 20), without traverse, in the paper of 14 June 2004, is acknowledged. It should be noted that claims will be examined insofar as they read on the elected Invention. Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim.

Claims 1-9 and 20 are under examination in the Instant Application.

Informalities

Information Disclosure Statement

In the Information Disclosure Statement, filed 15 September 2003, two citations were lined through by the examiner because they are non-published applications and may be indicative of privileged information.

No action is necessary.

Claim Rejections/Objections

35 *USC § 112, second paragraph -indefinite claim language*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112-second paragraph because the scope of the claimed cell is indeterminate. Claims 6 and 7 may reasonably be interpreted as encompassing naturally-occurring cells, including those found in multicellular organisms. It is unclear if the claims are limited to an isolated host cell or host cells in the context of a transgenic organism, including, possibly, a human. Amending independent claims to read "isolated," or "purified," etc. would be remedial.

Claim Rejections - 35 USC § 112, first paragraph – scope of enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 20 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, complementary polynucleotides, cells and membranes comprising SEQ ID NO: 1 and nucleic acids encoding SEQ ID NO: 2, does not enable variants of SEQ ID NO: 1. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims.

The specification does not reasonably provide enablement for use of variants of SEQ ID NO: 1 as recited in claims 1-9 and 20. The specification embraces numerous variants of the claimed polynucleotides and thus encompasses numerous undefined variants of SEQ ID NO: 1 without precise recitations of structure and function for each. Claims 1-9 and 20 read on polynucleotides that are at least 80% identical to SEQ ID NO: 1 over its entire length.

Claims 1-9 and 20 are directed to TR7 polynucleotides encoding SEQ ID NO: 2, complementary nucleotides and cells and expression systems for making the polypeptide of SEQ ID NO: 2. The polypeptide of SEQ ID NO: 2 has been shown by applicants to be a cytokine/Death receptor (US Patent 6,660,839) involved in B-cell growth, a fact recently confirmed by others (Schmidt, et al, 2003, J. Exp. Med., 197(1): 51-62). However, the specification is not enabling for the full scope of the claimed polynucleotides, wherein the polynucleotides and encoded amino acids are 80% identical to SEQ ID NO: 1 and 2, respectively, with the assurance that enabled proteins that are functionally equivalent to SEQ ID NO: 2 can be made without undue experimentation and with the assurance that they would have the desired properties of the TR7 polypeptide. There are no examples of what specific polynucleotides and polypeptides fall within the range of those that would be 80% identical. Furthermore, since the claims do not require the variants to have activity, the claims embrace inactive variants. The specification does not disclose how to use such inactive variants. The specification fails to provide any guidance on how to produce a peptide which is at least 80% identical to SEQ ID NO: 2 and yet retains the function of SEQ ID NO: 2. Likewise, there are no

discussions or working examples, in the instant case, as to what bases are necessary to maintain the functional characteristics of the claimed polynucleotide.

The instant case claims altering as much as 20% of the claimed polynucleotide(s). Although cytokine receptor family members share several common structural features, relevant art (Curfs, et al, 1997, Clin. Microbiol. Rev., 10(4): 742-780, esp. 773-776) shows that members of a class having high homology do not always share a specific and substantial functional attribute or utility, despite having structural features in common. Cytokine receptors, as a group, are quite homogeneous in structure; yet they are pleiotropic in their effects within cells and tissues (Curfs, et al, 1997, Clin. Microbiol. Rev., 10(4): 742-780, page 773). It is not known specifically how the claimed sequences might differ from the enabled reference sequence and still function in the same way as SEQ ID NO: 2; The literature would seem to indicate that the possible effect of changing only a few amino acids in a polypeptide cannot often be predicted. Murdoch and Finn (2000, Blood, 15(95): 3032-3043) discuss families of cytokine receptors in which members have very high homologies yet very different ligand binding affinities and selectivities. This serves to demonstrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of a protein. Point mutations in cytokine receptors further serves to illustrate this fact, since a single amino acid mutation can change the affinity of a cytokine receptor for its cognate ligand or inactivate it (Allende, et al, 2001, Clin. Diagn. Lab. Immunol., 8(1): 133-137). These examples and others serve to demonstrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of a cytokine receptor.

In summary, the specification does not provide a description of a repeatable process of producing, nor of working examples of making, the claimed nucleotides whose sequences deviate from the disclosed sequence (SEQ ID NO: 1) by as much as 20%. In addition, as discussed above, the predictability of the art is low with regards to the knowledge of what effects altering as much as 20% of the sequence of a polynucleotide would have on that polynucleotide and polypeptides produced from that polynucleotide. For this reason, undue experimentation would be required to determine a structure-function relationship for each possible polynucleotide and polypeptide encompassed by the claims.

Due to the large quantity of experimentation necessary to determine an activity or property of the claimed polynucleotides such that it can be determined how to use the claimed polynucleotides and disclosed polypeptides and to screen for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to testing variants, the complex nature of the invention, and the breadth of the claims which fail to recite particular biological activities--undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 USC § 112, first paragraph – Written Description.

Claims 1-9 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1-9 and 20 are directed to the polynucleotide of SEQ ID NO: 1, encoding the TR7 polypeptide of SEQ ID NO: 7. Dependent claims are directed to cells comprising SEQ ID NO: 1 and processes for recombinantly producing the polypeptide of SEQ ID NO: 2.

The specification teaches a polynucleotide (SEQ ID NO: 1) and a polypeptide (SEQ ID NO: 2). However, the specification does not teach functional or structural characteristics of all polypeptides used for the claimed methods. The description of one polynucleotide encoding a TR7 polypeptide (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of all encompassed TR7 polynucleotides, and therefore, would not know how to use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polynucleotide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 and a polypeptide comprising the amino acid sequence of SEQ ID NO:2, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion: Claims 1-9 and 20 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

20 September 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER